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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	30

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/518,813	Applicant(s) JOSEPH ET AL.	
File Copy	Examiner Jon D Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14,15,26-42 and 57-65* is/are pending in the application.

4a) Of the above claim(s) *3-6,9,14,26-42 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,8,10,11,15 and 58-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. The Response dated September 29, 2003 (Paper No. 29) is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

3. Claims 1-11, 14-15, 26-42 and 57 were pending. Applicants amended claims 1-5, 7-8, 10-11 and 15. Applicants added new claims 58-65. Therefore, claims 1-11, 14-15, 26-42 and 57-65 are pending.

4. Claims 3-6, 9, 14, 26-42 and 57 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim (e.g., see Paper No. 20, see also Paper No. 26, page 5, section I. on Preliminary Matters; see also Paper No. 29, Page 8).

5. Therefore, claims 1-2, 7-8, 10-11 and 15 and 58-65 are pending and examined on the merits in this action.

Election/Restriction

6. Applicant's election of species in Paper No. 29 is acknowledged.

7. The election was made without traverse and, as a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Withdrawn Objections/Rejections

8. All previous rejection and/or objections are withdrawn in view of Applicants' amendments and/or arguments.

New Rejections

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-2, 7-8, 10-11 and 15 and 58-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claims 1, 15**, the term "second library of individual proteins and polypeptides" is vague and indefinite. For example, it is not clear what the "second" is referring to? If second refers to "library of individual proteins and polypeptides" then the Examiner asks where is the "first" library of individual proteins and polypeptides? Applicants are requested to clarify. Therefore, claims 1, 15 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. **Claim 1** recites the limitation "the protein or polypeptide" in the 7th line. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

C. **Claim 1** recites the limitation "the polynucleotide" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

D. **Claim 1** recites the limitation "the first library" in the last line. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

E. For **claims 2**, the phrase "biological activity selected from the group consisting of an enzymatic protein or polypeptide modification" is vague and indefinite. For example, it is not clear how an "enzymatic protein" represents a "biological activity" (i.e., a "protein" is not an "activity", a protein is a chain of amino acids). Consequently, a person of skill in the art would not know what "activity" is intended by this protein e.g., cleavage of substrate, unfolding of tertiary structure, aggregation, etc.). Furthemore, it is also not clear what is doing the "binding" or "modulating" or "modification." Consequently, the metes and bounds of the claimed invention cannot be determined. Applicants are requested to clarify and/or correct. Therefore, claim 2 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

F. **Claim 10** recites the limitation "the proteins and polypeptides" in the second line. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 10 and all dependent claims are rejected under 35 USC 112, second paragraph.

G. **Claim 11** recites the limitation "the polynucleotides" in the second line. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 11 and all dependent claims are rejected under 35 USC 112, second paragraph.

H. For **claim 16**, it is not clear how a polynucleotide in step (i) could take the "form" of a cell colony or a plaque? Cell colonies and plaques consist of many cellular constituents including proteins and lipids that do not resemble polynucleotides. Applicants are requested to clarify and/or correct. Therefore, claims 16 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

I. **Claim 15** recites the limitation "the second library" in step (iii). There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 15 and all dependent claims are rejected under 35 USC 112, second paragraph.

J. **Claim 15** recites the limitation "the array" in step (iv). There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 15 and all dependent claims are rejected under 35 USC 112, second paragraph.

K. For **claims 58**, the phrase "the second library of individual proteins and polypeptides is formed by in vitro transcription and translation of an individual protein or polypeptide from each bacterial cell colony in step (ii)" is vague and indefinite. For example, it is not how "an individual protein or polypeptide" can undergo transcription and translation? The Examiner contends that nucleic acids can only undergo transcription and translation. Applicants are requested to clarify and/or correct. Therefore, claims 58 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

L. For **claims 58**, the phrase "the biological activity of interest in step (iii) is post-translational modification of a protein or polypeptide from a tissue extract" is vague and indefinite. For example, it is not clear if Applicant intends the library members to be from the tissue extract and hence undergo post-translation modification or the target sample that is interacting with the library members to be from a tissue sample and hence undergo post-translational modification i.e., it is not clear if the tissue extract refers to the library members or to the target proteins or to some other constituent. Applicants are requested to clarify and/or correct. Therefore, claims 58 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-2, 7-8, 10-11 and 15 and 58, 60-62 and 64-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al (U.S. Patent No. 5,824,485) (Filing Date is **April 24, 1996**).

For ***claim 1***, Thompson et al (see entire document) disclose methods for generating and screening novel metabolic pathways including methods for mixing and

cloning genetic materials from a plurality of species of organisms in combinatorial gene expression libraries to generate novel metabolic pathways (see Thompson et al, abstract), which anticipates claim 1. For example, Thompson et al disclose a method of screening proteins and polypeptides to identify a protein or polypeptide having a biological activity of interest (e.g., see Thompson et al, section 5.2.3, especially column 37, lines 30-36, "The combinatorial gene expression libraries of the invention may be pre-screened or screened by a variety of methods, including but not limited to, visual inspection, automated image analysis, hybridization to molecular beacon DNA probes (Tyagi et al. 1996, Nature Biotechnol, 14:303-308) fluorescence activated cell sorting (FACS) and magnetic cell sorting (MACS)"; see also column 3, section 2.2, especially lines 46-50, "Gene expression libraries are used to identify, investigate and produce the target molecules. Expression cloning has become a convention method for obtaining the target gene encoding a single protein without knowing the protein's physical properties"; see also column 4, paragraphs 1-2; see also section 5.2, especially column 32, last paragraph, "While standard methods of screening expression libraries, such as antibody binding and ligand binding, can ... be used"; see also column 46, section 5.4.8). Thompson et al further disclose **(i)** forming a first library of polynucleotide clones (e.g., see Thompson et al, columns 12, lines 25-26, "Any combinatorial gene expression library of the invention may be amplified, replicated, and stored. Amplification refers to culturing the initial host organisms containing donor DNA so that multiple clones of the host organisms are produced. Replication refers to picking and growing of individual clones in the library"; see also column 29, paragraphs 1-4; see also column 33, paragraphs 1-2; see also column

50, section 5.4.14; see also claims e.g., claim 36). Thompson et al further disclose **(ii)** expressing an individual protein or polypeptide from each clone in the first library to form a second library of individual proteins and polypeptides therefrom (e.g., see Thompson et al, column 3, section 2.2, especially column 3, lines 47-50, "Expression cloning has become a conventional method for obtaining the target gene encoding a single protein without knowing the proteins' physical properties. Many proteins identified by screening gene expression libraries ... are potential disease targets e.g., receptors ... and signal-transducing proteins"; see also column 5, lines 39-47). Thompson et al further disclose **(iii)** assaying the second library to select an individual protein or polypeptide in the second library having a biological activity of interest (e.g., see Thompson et al, section 5.2, especially column 32, last paragraph, "While standard methods of screening expression libraries, such as antibody binding and ligand binding, can be used"; see also section 2.2, especially column 3, lines 46-50; see also column 5, lines 44-45; see more generally section 5.2). Finally, Thompson et al further disclose **(iv)** identifying the protein or polypeptide selected in step (iii) by sequencing the polynucleotide from the first library that encodes he selected protein or polypeptide (e.g., see Thompson et al, section 5.2; see especially column 4, lines 39-40; see especially column 60, paragraph 2, "Six clones were isolated that were positive to starch digestion ability ... one clone was found to inhibit the growth of *S. aurantiaca*. This clone was subjected to further analysis, including DNA sequence analysis"; see also column 10, lines 8-18, "Once a desirable activity ... is identified ... [t]he genes ... are immediately available for sequencing").

For ***claim 2***, Thompson et al further disclose "enzymatic", "binding" and "metabolism modulating" activities (e.g., see Thompson et al, especially column 32, last paragraph, "While standard methods of screening expression libraries, such as antibody binding and ligand binding, can be used"; see also column 33, line 35; see also column 4, paragraph 1; see also column 41, section 5.3.5.).

For ***claim 7***, Thompson et al further disclose the use of an array (e.g., see Thompson et al, column 28, last paragraph, "Alternatively, the library may be stored in an ordered array. The bulk of the library can be plated out at low density to allow formation of single, discrete plaques or colonies, followed by transfer of individual plaques or colonies into the wells of coded multi-well master plates e.g., 96-well"; see also column 35, line 20; see also column 48, lines 42-45; see also column 49, line 47; see also column 50, lines 8-15; see also column 57, lines 30-40; see also column 61, paragraph 1).

For ***claim 8***, Thompson et al further disclose the use of solid supports (e.g., see Thompson et al, column 35, paragraph 3, disclosing the use of magnetic microspheres).

For ***claim 10***, Thompson et al further disclose the use of "glass" beads (e.g., see Thompson et al, column 56, line 27).

For ***claim 11***, Thompson et al disclose in vitro transcription and translation (e.g., see Thompson et al, column 18, paragraph 1, "Any cell type may be used, including those that have been cultured *in vitro*"; see also column 21, paragraph 2; see also column 23, paragraph 3; see also column 28, paragraph 4; see also column 33, paragraph 1, "The

libraries may also be used directly with a target in both in vivo and in vitro assays"; see also column 58, paragraph 2).

For ***claim 15***, Thompson et al disclose **(i)** generating a first library of polynucleotides in the form of clones selected from the group consisting of DNA molecules, RNA molecules, cell colonies and plaques (e.g., see Thompson et al, columns 12, lines 25-26; see also column 29, paragraphs 1-4; see also column 33, paragraphs 1-2; see also column 50, section 5.4.14; see also claims e.g., claim 36). Thompson et al further disclose **(ii)** expressing a polynucleotide from each clone in the first library using in vitro translation to generate a second library of individual proteins and polypeptides (e.g., see Thompson et al, column 3, section 2.2, especially column 3, lines 47-50; see also column 5, lines 39-47; see also column 18, paragraph 1; see also column 21, paragraph 2; see also column 23, paragraph 3; see also column 28, paragraph 4; see also column 33, paragraph 1; see also column 58, paragraph 2). Thompson et al further disclose **(iii)** dispensing an aliquot of each protein or polypeptide in the second library into a specific locus in a multi-well plate or a solid phase to form a protein and polypeptide array (e.g., see Thompson et al, column 28, last paragraph; see also column 35, line 20; see also column 48, lines 42-45; see also column 49, line 47; see also column 50, lines 8-15; see also column 57, lines 30-40; see also column 61, paragraph 1). Thompson et al further disclose **(iv)** contacting the array generated in step (iii) with a material selected from the group consisting of a cell extract, a tissue extract, a cell sample or tissue sample and **(v)** assaying each protein and polypeptide in the array to select an individual protein or polypeptide that interacts with the material contacting the array

(e.g., see Thompson et al, column 33, lines 33-34, "The term "target" refers generally to whole cells as well as macromolecules"; see also column 5, line 59; see especially column 34, paragraph 3, "In yet another embodiment of he invention, indicator cells may be used to signal the production of a desirable activity or compound, thereby enabling identification and/or isolation of productive cells in the library. Whole live of fixed indicator cells, or cellular fractions thereof may be mixed ... with individual or pools of library cells"). Thompson et al further disclose identifying the individual proteins or polypeptide selected in step (v) by sequencing (e.g., see Thompson et al, section 5.2; see especially column 4, lines 39-40; see especially column 60, paragraph 2, "Six clones were isolated that were positive to starch digestion ability ... one clone was found to inhibit the growth of *S. aurantiaca*. This clone was subjected to further analysis, including DNA sequence analysis"; see also column 10, lines 8-18, "Once a desirable activity ... is identified ... [t]he genes ... are immediately available for sequencing"). Finally, Thompson et al disclose an interaction selected from the group consisting of modification of a protein or polypeptide in the array, binding of a protein or polypeptide in the array to a molecule from a cell, and binding of a protein or polypeptide in the array to a molecule from a tissue (e.g., see Thompson et al, especially column 32, last paragraph, "While standard methods of screening expression libraries, such as antibody binding and ligand binding, can be used"; see also column 33, line 35; see also column 4, paragraph 1; see also column 41, section 5.3.5.).

For ***claims 58, 60-61, 62 and 64-65***, Thompson et al disclose the use of bacterial cell colonies (e.g., see Thompson et al, Figure 9 wherein Thompson et al disclose *E.coli*

bacterial cells). Thompson et al further disclose in vitro transcription and translation (e.g., see Thompson et al, figure 9, see also (e.g., see Thompson et al, column 18, paragraph 1, "Any cell type may be used, including those that have been cultured *in vitro*"; see also column 21, paragraph 2; see also column 23, paragraph 3; see also column 28, paragraph 4; see also column 33, paragraph 1, "The libraries may also be used directly with a target in both in vivo and in vitro assays"; see also column 58, paragraph 2). Finally, Thompson et al disclose post-translational modification (e.g., see Thompson et al, paragraph bridging column 18, last paragraph; see also column 19, paragraph 1-3; see also column 4, paragraph 2; see also). Finally, Thompson et al disclose the use of tissue extracts (e.g., see Thompson et al, column, line 52, "Many proteins identified by screening gene expression libraries prepared from human and mammalian tissues are potential disease targets").

11. Claims 1-2, 7, 11, 15 and 58-64 are rejected under 35 U.S.C. 102(e) as being anticipated by McCarthy et al (U.S. Patent No. 5,952,171) (Filing Date is **November 19, 1996**).

For ***claim 1***, McCarthy et al (see entire document) disclose methods of identifying (i.e., screening) genes encoding secreted or membrane-associated proteins (see McCarthy et al, abstract), which anticipates claim 1. For example McCarthy et al disclose **(i)** forming a first library of polynucleotide clones (e.g., see abstract, step (c), "transforming bacterial cells with said ligated DNA to create a bacterial cell clone library"; see also step (e) wherein a mammalian cell clone library is formed; please note that both libraries anticipate applicants' claims). McCarthy et al further disclose **(ii)** expressing an

individual protein or polypeptide from each clone in the library to form a second library of individual proteins and polypeptides therefrom and **(iii)** assaying the second library to select an individual protein or polypeptide in the second library having a biological activity of interest (e.g., see McCarthy et al, abstract, step (d), "identifying a clone in the mammalian cell clone library which express alkaline phosphatase" wherein the "alkaline phosphatase" activity represents the biological activity of interest). Finally, McCarthy et al further disclose **(iv)** identifying the protein or polypeptide selected in step (iii) by sequencing the polynucleotide from the first library that encodes the selected protein or polypeptide (e.g., see McCarthy et al, abstract, step (g), "isolating and sequencing a portion of the mammalian cDNA present in the bacterial cell library clone identified in step (g) to identify a mammalian cDNA encoding a mammalian protein having a signal sequence).

For ***claim 2***, McCarthy et al disclose an enzymatic protein like alkaline phosphatase (e.g., see McCarthy et al, abstract).

For ***claim 7***, McCarthy et al disclose an array (e.g., see McCarthy et al, Example 1, especially, column 8, lines 19-21 disclosing the use of a 96 well plate).

For ***claim 11***, McCarthy et al disclose in vitro transcription and translation (e.g., se McCarthy et al, column 1, lines 22-26; see also example 1).

For ***claim 15***, McCarthy et al disclose **(i)** generating a first library of polynucleotides in the form of clones selected from the group consisting of DNA molecules (e.g., see McCarthy et al, Example 1, discloses a library of signal peptides at different positions in a microtiter plate; see especially column 8, lines 19-21). McCarthy

et al further disclose **(ii)** expressing a polynucleotide from each clone in the first library using in vitro translation to generate a second library of individual proteins and polypeptides (e.g., see McCarthy et al, Example 1 wherein "potential" signal peptides attached to a human placental alkaline phosphatase are expressed). McCarthy et al further disclose **(iii)** dispensing an aliquot of each protein or polypeptide in the second library into a specific locus in a multi-well plate or a solid phase to form a protein and polypeptide array (e.g., see McCarthy et al, column 8, lines 19-29, "thus, each well of each 96 well plate containing COS7 cell receiving DNA representing on individual cDNA clone from the cDNA library in ptrAP3 ... Cells were incubated overnight"). McCarthy et al further disclose **(iv)** contacting the array generated in step (iii) with a material selected from the group consisting of a cell extract, a tissue extract, a cell sample, and a tissue sample (e.g., see McCarthy et al, Example 1 wherein the "cell sample" are the COS7 cells). McCarthy et al further disclose **(v)** assaying each protein and polypeptide in the array to select an individual protein or polypeptide that interacts with the material contacting the array in step (iv) (e.g., see McCarthy et al, column 8, Step 5, lines 29-39 wherein alkaline phosphatase activity is measured to see if any of the members of the protein library have "interacted" with the COS7 cells (e.g., bound to the COS7 cell membrane and subsequently been secreted), which is subsequently detected by measuring the alkaline phosphatase activity of the supernatants. McCarthy et al further disclose identifying the individual protein or polypeptide selected in step (v) by sequencing the polynucleotide that encodes the selected protein or polypeptide (e.g., column 8, lines 40-50, step 6, "Sequencing and Analysis of Positive Clones"). Finally,

McCarthy et al further disclose an interaction that includes binding to a membrane and cleavage of the cell peptide.

For ***claims 58, 60, 62 and 64***, McCarthy et al disclose **(i)** transforming *E. coli* bacterial cells (e.g., see McCarthy et al, Example 1), **(ii)** the use of in vitro transcription and translation to form an individual protein or polypeptide from each bacterial cell colony (e.g., see McCarthy et al, Example 1) and **(iii)** the cleavage of a signal sequence to allow excretion and production of mature alkaline phosphatase. In this scenario, the COS cells represent the "tissue extract" i.e., the cells were extracted from African green monkey kidneys. Please note that the reference does not explicitly state that the signal sequence is cleaved from the alkaline phosphatase, however, the mature alkaline phosphatase could not be produced without said cleavage. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claims 59 and 63***, the Examiner notes that the library of signal sequences also "interact" with IgG domains that were derived from human fetal brain tissue (e.g., see McCarthy et al, columns 9-10 and figure 6; see also column 6, line 27-28, "cDNA ... was prepared ... from human fetal brain tissue").

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jon D. Epperson, Ph.D.
January 26, 2004

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